

Shortage of Valsartan Formulations

Date: 7th June 2019

Description of products affected

Valsartan is an angiotensin II receptor antagonist (AIIRA) licensed for the treatment of patients with:

- Hypertension.
- Symptomatic heart failure.
- Post- myocardial infarction (MI) with left ventricular failure or left ventricular systolic dysfunction (LVSD).

Licensed doses range from 40mg to 320mg per day given once or twice daily depending on indication.

It is one of several AIIRAs on the UK market which are all licensed for the treatment of hypertension but differ in their other licensed indications.

Background

- There have been intermittent supply problems with all strengths of valsartan formulations (including both capsules and tablets).
- Our Medicines Optimisation Team has managed to ascertain the following availability from manufacturers as of 5th June 2019:
 - *AAH – Valsartan 40mg capsules available.*
 - *Alliance HC – Valsartan 320mg tablets available.*
 - *Mylan – Valsartan 40mg tablets currently in quality control and due to be released shortly.*
 - *Phoenix – Valsartan 40mg capsules and 320mg tablets available.*
- There is currently only the broad anticipated resolution date of July to September 2019.
- Suppliers of alternative AIIRAs have been contacted to determine if they have sufficient stock availability and currently both Losartan and Candesartan are available from the 3 major wholesalers: AAH, Alliance HC and Phoenix.

Alternative agents and suggested management options

- The patient should be encouraged to try several pharmacies in order to fulfil the prescription as different pharmacies use a range of wholesalers and distributors. The patient may wish to ring pharmacies in advance of attending to ascertain availability.

- The decision about what to do will need to be individualised to each patient.
- Within primary care the formulary choices which should be considered:
 - **1st line AIIRA is Losartan**
 - **2nd line choice is Candesartan.**
- **In Hypertension:** Consider switching patient to either losartan or candesartan in the first instance.
- **In Heart Failure:** Consider switching patients to either losartan or candesartan. These are the only AIIRAs licensed for heart failure.
- **Post-MI with left ventricular failure or left ventricular systolic dysfunction (LVSD):** There are no other AIIRAs licensed for use in the post-MI setting and specialist advice should be sought before switching to an alternative.

Dose equivalence and conversion

- There is limited information on direct dose-equivalences of AIIRAs and clinical judgement will be required.
- When changing from one drug to another, consideration should be given to where on the dosing range the current dose falls, i.e. bottom, middle or top of range.
- When switching patient to alternate AIIRAs, blood pressure and signs of symptoms of the underlying disorder should be monitored to guide dosing. Table 1 provides approximate dose conversions for AIIRAs.
- It is important to involve any patients (and their carers, as appropriate) in the discussion regarding any planned change to their medication **BEFORE** making the change.
- If switching from a twice daily valsartan dose to a once daily dose of an alternative such as losartan or candesartan, the patient should be advised of this to reduce the risk of a dosing error.
- If any of the recommendations are not clinically acceptable or there is any uncertainty about what to do or how to do it then management options should be discussed with the responsible consultant specialist depending on the indication.

Table 1 – Approximate Dose Conversions for AIIRAs

AIIRA	Approximate Dose conversions (monitor BP following switch and adjust as needed)			
Valsartan	40mg DAILY*	80mg DAILY*	160mg DAILY*	320mg DAILY*
Candesartan	4mg DAILY	8mg DAILY	16mg DAILY	16-32mg DAILY
Losartan**	25mg DAILY	50mg DAILY	100mg DAILY	-

* Dose may be given as two divided doses depending on indication.

** The target dose of losartan for heart failure is 150mg daily if tolerated.

References

1. Joint Formulary Committee (2019) *British National Formulary*. Available at: <http://bnf.nice.org.uk> (Accessed: 6 June 2019)
2. SPCs for Valsartan preparations accessed via electronic Medicines Compendium. Available at: <https://www.medicines.org.uk/emc/product/7118/smpc> (Accessed: 6 June 2019)
3. SPCs for Losartan preparations accessed via electronic Medicines Compendium. Available at: <https://www.medicines.org.uk/emc/product/7062/smpc> (Accessed: 6 June 2019)
4. SPCs for Candesartan preparations accessed via electronic Medicines Compendium. Available at: <https://www.medicines.org.uk/emc/product/4083/smpc> (Accessed: 6 June 2019)
5. NHS Cambridgeshire and Peterborough Think Prescribing Newsletter May 2016. Available at: <https://www.cambridgeshireandpeterboroughccg.nhs.uk/easysiteweb/getresource.axd?assetid=3295&type=0&servicetype=1> (Accessed: 6 June 2019)
6. UKMi Shortage of Valsartan Products Memo March 2014. Available at: <https://www.sps.nhs.uk/articles/shortage-of-valsartan/> (Accessed: 6 June 2019)
7. NHS Cambridgeshire and Peterborough Formulary. Available at: <http://www.cambridgeshireandpeterboroughformulary.nhs.uk/chaptersSubDetails.asp?FormularySectionID=2&SubSectionRef=02.05.05.02&SubSectionID=A100&drugmatch=2415#2415> (Accessed: 19 February 2019)

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